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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,975	01/18/2002	Limin Li	STAN-216	5176

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EXAMINER	
FETTEROLF, BRANDON J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,975	LI ET AL.	
	Examiner	Art Unit	
	Brandon J. Fetterolf, PhD	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-16,22-25,31,32 and 37-45* is/are pending in the application.

4a) Of the above claim(s) *7-16,22-25,31,32,37-42,44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-6 and 43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Li et al.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/21/2005 has been entered.

Claims 1, 4-16, 22-25, 31-32 and 37-45 are currently pending.

Claims 7-16, 22-25, 31-32, 37-42 and 44-45 are withdrawn from consideration as being drawn to non-elected inventions.

Claims 1, 4-6 and 43 are currently under consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-6 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of antibodies that bind to a genus of polypeptides comprising a ubiquitination domain and/or a functional fragment thereof referred to as TSG101. However, the written description in this case only sets forth antibodies which bind to one species of polypeptide comprising a ubiquitination domain referred to as human TSG101 consisting of the amino acid sequence set forth in SEQ ID NO: 1.

The specification teaches (page 12, 3rd paragraph) that specific polypeptides of the invention include, but are not limited to, any isolated polypeptide comprising a ubiquitination-regulating

domain which regulates ubiquitination, e.g., via regulating conjugases (E2 enzymes). With regards to the ubiquitination-regulating domain, the specification teaches that ubiquitination-regulating domain not only includes an amino acid sequence of an ubiquitination-regulating domain of a TSG101 protein, but also any functional fragment of a ubiquitination-regulating domain of a TSG101 protein comprising amino acids 10-140, 20-140, 30-140, 40-140, 1-160 ... 50-250 or 1-250 of TSG101 (page 11, 4th paragraph to page 12, 2nd paragraph). However, the written description only reasonably conveys antibodies that bind to one species of polypeptide consisting of a ubiquitination domain referred to as human TSG101 consisting of the amino acid sequence set forth in SEQ ID NO: 1; and is not commensurate with the full scope of antibodies which bind to any and/or all polypeptides comprising a ubiquitination domain and/or a functional fragment thereof of a TSG101 protein. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cNDA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., __F.3d__,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genus. That is, the specification provides neither a representative number of TSG101 proteins that encompass the genus of polypeptides, nor does it provide a description of structural features that are common to the polypeptides. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of one species of TSG101 protein is insufficient to describe the genus. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure(s) of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Applicants should further refer to Example 13 of the revised interim Written Description Guidelines regarding protein variant language (see http://www.uspto.gov/web/menu/written.pdf>).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Therefore, only antibodies that bind to one species of polypeptide comprising a ubiquitination domain referred to as human TSG101 consisting of the amino acid sequence set forth in SEQ ID NO: 1, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

In response to this rejection, Applicant's assert (Remarks, 10/31/2005, Page 8) that the specification provides reduction to practice of a representative number of species (see, for example, the fragments listed on page 24, last paragraph of the specification), discloses functional characteristics shared by all of the species and a correlation between function and structure. For example, Applicants submit that the specification (page 12, lines 3-4) recites "a functional fragment of an ubiquitination-conjugase-like Ubc domain refers to any fragment of the Ubc domain that regulates ubiquitination." As such, Applicants assert that the functional characteristics shared by all of the species encompassed by the claimed genus "...ubiquitination-regulating domain, or a functional fragment thereof..." is the ability to regulate ubiquitination. Moreover, Applicants point to page 26 of the specification which discloses a method by which one can determine which

fragments of a ubiquitination-regulating domain regulates ubiquitination. Thus, Applicants contend that the specification teaches one of skill in the art how to identify functional fragments of an ubiquitination- regulating domain. Furthermore, Applicants argue that they have identified a correlation between function and structure as shown in Figure 3(a) of the speciation.

These arguments have been carefully considered, but are not found persuasive.

In response to Applicants arguments that the specification provides reduction to practice of a representative number of species (see, for example, the fragments listed on page 24, last paragraph of the specification), discloses functional characteristics shared by all of the species and a correlation between function and structure, the Examiner concedes that the specification provides the complete sequence of the ubiquitination-regulating domain of human TSG101 (page 24, last paragraph) and deletion fragments of human TSG101 (Figure 3A). However, the specification does not appear to provide a written description for any and/or all functional fragments of a polypeptide comprising an ubiquitination-regulating domain comprising the amino acid sequence of SEQ ID NO: 1. In this instance, the transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). Thus, while one of skill in the art may reasonably convey that Applicants were in possession of the claimed genus of polypeptide consisting of an ubiquitination-regulating domain or function fragment thereof of a human TSG101 protein consisting of the amino acid sequence of SEQ ID NO: 1, wherein the fragment regulates ubiquitination, Applicants have not reasonably conveyed that they were in possession of the presently claimed genus. Moreover, while Applicants contend that the specification teaches one of skill in the art how to identify functional fragments of an ubiquitination- regulating domain, Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115). As such, the specification

describing to one of skill in the art how to identifying function fragments does not reasonably convey that Applicants were in possession of the claimed genus.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (IDS, US 5,891,668, 1999).

Li. et al. teach antibodies which have been raised to normal or mutated forms of TSG101 (column 8, line 59-63). Specifically, the patent teaches antibodies that specifically recognize the coiled domain, leucine zipper and proline rich domains of TSG101 (column 8, lines 64 to column 9, line 4). With regards to TSG101, Li et al. provide both the mouse TSG101 and the human homolog (column 3, lines 26-38, see below, human homolog). Although the reference does not specifically teach that the antibody binds to a polypeptide comprising a ubiquitination-regulating domain, the claims are drawn to the product *per se* and inherently, such an antibody would bind to a polypeptide comprising a ubiquitination-regulating domain. Thus, the claimed peptide appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

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Patent No. 5891668
APPLICANT:  LI, Limin
APPLICANT:  COHEN, Stanley N
US-08-670-274B-4

  Query Match             97.8%;  Score 2002;  DB 2;  Length 380;
  Best Local Similarity   100.0%;  Pred. No. 3e-155;
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  Matches  380;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy          11 MVSKYKYRDLTVRETVNVITLYKDLKPVLDSYVFNDGSSRELMNLTGTIPVPYRGNTYNI 70
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db           1 MVSKYKYRDLTVRETVNVITLYKDLKPVLDSYVFNDGSSRELMNLTGTIPVPYRGNTYNI 60

Qy          71 PICLWLLDTYPYNPPICFVKPTSSMTIKTGKHVDANGKIYLPYLHEWKHPQSDLLGLIQV 130
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          61 PICLWLLDTYPYNPPICFVKPTSSMTIKTGKHVDANGKIYLPYLHEWKHPQSDLLGLIQV 120

Qy         131 MIVVFGDEPPVFSRPISASYPPYQATGPPNTSYMPGMPGGISPYPSGYPPNPSGYPGCPY 190
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         121 MIVVFGDEPPVFSRPISASYPPYQATGPPNTSYMPGMPGGISPYPSGYPPNPSGYPGCPY 180

Qy         191 PPGGPYPATTSSQYPSQPPVTTVGPSRDGTISEDTIRASLISAVSDKLRWRMKEEMDRAQ 250
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         181 PPGGPYPATTSSQYPSQPPVTTVGPSRDGTISEDTIRASLISAVSDKLRWRMKEEMDRAQ 240

Qy         251 AELNALKRTEEDLKKGHQKLEEMVTRLDQEVAEVDKNIELLKKKDEELSSALEKMENQSE 310
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         241 AELNALKRTEEDLKKGHQKLEEMVTRLDQEVAEVDKNIELLKKKDEELSSALEKMENQSE 300

Qy         311 NNDIDEVIIPTAPLYKQILNLYAEENAIEDTIFYLGEALRRGVIDLDVFLKHVRLLSRKQ 370
               ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         301 NNDIDEVIIPTAPLYKQILNLYAEENAIEDTIFYLGEALRRGVIDLDVFLKHVRLLSRKQ 360

Qy         371 FQLRALMQKARKTAGLSDLY 390
               ||||||||||||||||||||
Db         361 FQLRALMQKARKTAGLSDLY 380
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Claims 1, 4-6 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Brie et al. (US 5,892,016, 1999).

Brie *et al.* teach a purified protein having an amino acid sequence having 100% identity to the amino acid sequence set forth in SEQ ID NO: 1 (Figures 1A-1B, *see* below). The patent further teaches antibodies including, but not limited to, polyclonal, monoclonal and chimeric which bind specifically to the polypeptide (column 17, line 15 to column 18, line 16). Furthermore, Brie et al. disclose that the antibodies can be used as a pharmaceutical agent for the prevention and or treatment of disease associated with expression of the polypeptide (column 16, lines 56-60). Although the reference does not specifically teach that the antibody binds to a polypeptide comprising a ubiquitination-regulating domain, the claims are drawn to the product *per se* and inherently, such an antibody would bind to a polypeptide comprising a ubiquitination-regulating domain. Thus, the claimed peptide appears to be the same as the prior art. The office does not have

the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

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OS   Homo sapiens.
PN   US5892016-A.
PD   06-APR-1999.
PF   23-JAN-1997;   97US-00786999.
PR   23-JAN-1997;   97US-00786999.
PA   (INCY-) INCYTE PHARM.
PI   Brie SL,  Goli SK;
SQ   Sequence 390 AA;

  Query Match             100.0%;  Score 2047;  DB 2;  Length 390;
  Best Local Similarity   100.0%;  Pred. No. 6.7e-149;
  Matches  390;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps
0;

Qy          1 MAVSESQLKKMVSKYKYRDLTVRETVNVITLYKDLKPVLDSYVFNDGSSRELMNLTGTIP 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MAVSESQLKKMVSKYKYRDLTVRETVNVITLYKDLKPVLDSYVFNDGSSRELMNLTGTIP 60

Qy         61 VPYRGNTYNIPICLWLLDTYPYNPPICFVKPTSSMTIKTGKHVDANGKIYLPYLHEWKHP 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 VPYRGNTYNIPICLWLLDTYPYNPPICFVKPTSSMTIKTGKHVDANGKIYLPYLHEWKHP 120

Qy        121 QSDLLGLIQVMIVVFGDEPPVFSRPISASYPPYQATGPPNTSYMPGMPGGISPYPSGYPP 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 QSDLLGLIQVMIVVFGDEPPVFSRPISASYPPYQATGPPNTSYMPGMPGGISPYPSGYPP 180

Qy        181 NPSGYPGCPYPPGGPYPATTSSQYPSQPPVTTVGPSRDGTISEDTIRASLISAVSDKLRW 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 NPSGYPGCPYPPGGPYPATTSSQYPSQPPVTTVGPSRDGTISEDTIRASLISAVSDKLRW 240

Qy        241 RMKEEMDRAQAELNALKRTEEDLKKGHQKLEEMVTRLDQEVAEVDKNIELLKKKDEELSS 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 RMKEEMDRAQAELNALKRTEEDLKKGHQKLEEMVTRLDQEVAEVDKNIELLKKKDEELSS 300

Qy        301 ALEKMENQSENNDIDEVIIPTAPLYKQILNLYAEENAIEDTIFYLGEALRRGVIDLDVFL 360
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        301 ALEKMENQSENNDIDEVIIPTAPLYKQILNLYAEENAIEDTIFYLGEALRRGVIDLDVFL 360

Qy        361 KHVRLLSRKQFQLRALMQKARKTAGLSDLY 390
              ||||||||||||||||||||||||||||||
Db        361 KHVRLLSRKQFQLRALMQKARKTAGLSDLY 390
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In reference to claims 1, 4-6 and 43 being rejected under under 35 U.S.C. 102(b) as being anticipated by Li et al. (IDS, US 5,891,668, 1999) or Brie et al. (US 5,892,016, 1999), Applicants assert (10/31/2005 Remarks) that Li et al. and Brie et al. each describe a genus of antibodies that bind to the full length TSG101. In contrast, Applicants contend that the present invention discloses a species of that genus (i.e., antibodies that bind specifically to the ubiquitination-regulating domain of human TSG101). As such, Applicants submit that a genus does not always anticipate a claim to a species within the genus, if the species is not specifically taught (See MPEP, 2131.02). Therefore, Applicants argue that since neither Li et al. nor Brie et al. teach or suggest the existence of a ubiquitination-regulating domain of human TSG101, neither of these references teach or suggest an antibody that binds to this region. Furthermore, Applicants assert that binding to the ubiquitination-regulating domain is not an inherent characteristic of the antibodies of Li et al. or Brie et al.. Applicants further contend that inherency may not be established by probabilities or possibilities and that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient. In re Rijckaert, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) and MPEP 2112 IV. "[T]he examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). As such, Applicants contend that due to the protein folding, ect., antibodies developed to the full length TSG101 may not necessarily bind to the ubiquitination-regulating domain.

These arguments have been carefully considered, but are not found persuasive.

In response to Applicants arguments that species does not anticipate a species, the Examiner agrees that a genus disclosed in the prior art does not always anticipate species as outlined in the MPEP 2131.02. However, Applicants have not provided a patentable difference between the antibody presently claimed and the ones disclosed in the prior art. In the instant case, the claims are drawn to an isolated antibody that binds to a polypeptide comprising (emphasis added) an ubiquitination-regulating domain, or a functional fragment thereof, of a human TSG101 protein comprising (emphasis added) the amino acid sequence recited in SEQ ID NO: 1. The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is

inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). Thus, there does not appear to be a patentable difference between an antibody which binds to a polypeptide fragment (100% identical from amino acids 11 to 390 of SEQ ID NO: 1) of the amino acid sequence recited in SEQ ID NO: 1 (Li, US 5,891,668, see sequence comparison) or an antibody which binds to a polypeptide that is 100% identical (see sequence comparison) to a polypeptide comprising the amino acid sequence recited in SEQ ID NO: 1, wherein the ubiquitination-regulating domain may comprise amino acid residues 50-140, 1-140 or 140-250 of SEQ ID NO: 1. With regard to Applicants contention that binding to the ubiquitination-regulating domain is not an inherent characteristic of the antibodies of Li et al. or Brie et al., the Examiner recognizes that inherency may not be established by probabilities or possibilities and that the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient. However, the claims are drawn to an isolated antibody that binds to a polypeptide comprising (emphasis added) an ubiquitination-regulating domain, or a functional fragment thereof, of a human TSG101 protein comprising (emphasis added) the amino acid sequence recited in SEQ ID NO: 1. The prior art teaches an antibody which binds to a polypeptide (100% identical from amino acids 11 to 390 of SEQ ID NO: 1) comprising a ubiquitination-regulating domain comprising the amino acid sequence recited in SEQ ID NO: 1 (Li, US 5,891,668, see sequence comparison) and an antibody which binds to a polypeptide that is 100% identical (see sequence comparison) to a polypeptide comprising a ubiquitination-regulating domain comprising the amino acid sequence recited in SEQ ID NO: 1, wherein the ubiquitination-regulating domain may comprise amino acid residues 50-140, 1-140 or 140-250 of SEQ ID NO: 1. Thus, the claimed antibody appears to be the same as the prior art. As stated in the prior Office Action (pages 7 and 8), the office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics

of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. (emphasis added) See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). Therefore, amended claims 1, 4 and 6 remain rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (IDS, US 5,891,668, 1999) and claims 1, 4-6 and 43 remain rejected under 35 U.S.C. 102(b) as being anticipated by Brie et al. (US 5,892,016, 1999)

Therefore, NO claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J. Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached on Monday through Friday from 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD
Examiner
Art Unit 1642

BF
May 16, 2006

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER